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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,473	03/28/2005	Jarmo Ruuhonen	0365-0625PUS1	8171
2292 7590 06/04/2008 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747				
EXAMINER CWERN, JONATHAN				
ART UNIT 3737		PAPER NUMBER		
NOTIFICATION DATE 06/04/2008		DELIVERY MODE ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary

Application No.

10/529,473

Applicant(s)

RUOHONEN, JARMO

Examiner

Jonathan G. Cwern

Art Unit

3737

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

Specification

The abstract of the disclosure is objected to because it improperly contains means language. In addition the words "Fig. 1" can be deleted from the end of the abstract. Correction is required. See MPEP § 608.01(b).

Claim Objections

Claims 1-17 are objected to because of the following informalities:

In claim 1, on line 8, "a second head" should be "said second head" if referring to the same second head from earlier in the claim. Also, "the location data" lacks antecedent basis.

In claim 2, it is unclear as to what further step in the method has been set forth.

In claim 4, "the response recorded by MEG or EEG" and "the effective stimulating field" lack antecedent basis. Also, in the phrase "the head surface" it is unclear which head is being referred to (first or second).

In claim 7, "the location data of such functional points of the brain" lacks antecedent basis.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim is rejected for two reasons. One, the phrase "or the like" is vague. It is unclear as to what is being referred to by this phrase. Secondly, it is unclear as to what is meant by "sending of internal structures by MRI". It is unclear as to how MRI "sends" internal structures.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5 and 7-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fox et al. (US 2003/0050527) in view of Vilsmeier (US 7194295).

Fox et al. show, a method for modeling different internal structures of a head, such as different parts of the brain, in order to focus magnetic stimulation and/or visualize the results of magnetic stimulation, MEG or EEG ([0025]-[0028]), the method comprising the step of determining the location of the internal structures, such as the different cerebral parts, of at least one first head (B) in a three-dimensional space by technical means, such as magnetic resonance imaging or computer-aided tomography ([0025]-[0028]), and determining the external structure (dimensions of the scalp surface

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are determined by the 3-D digitizer, [0025]-[0028]). It should be noted that while using the 3-D digitizer, only the external dimensions of a head are determined, and not the internal dimensions, and this does not require the use of MRI. Fox et al. also show, TMS localized in relation to anatomical marker points on the head surface ([0028]); measuring external head dimensions with a pointer with electrical position sensor means ([0028]); locating functional areas of the brain with the help of magnetic stimulation ([0087]).

Fox et al. fail to show, using a model of a second head for the external dimensions, and scaling the internal structure for the present patient (A) to fit to the model of previously imaged external structure (B), so that anatomical images do not need to be acquired for the present patient (A); image data is scaled by moving pixels; deforming the image by minimizing distance between points, and accepting the minimization even when the distance between the points is not zero; performing measurements on a plurality of test persons; selecting the standard model from a library of images from a plurality of different people; and the scaling is linear or nonlinear.

Vilsmeier discloses a method for computer assisted medical navigation or treatment planning. Vilsmeier teaches, using a model of a second head for the external dimensions, and scaling the internal structure for the present patient (A) to fit to the model of previously imaged external structure (B), so that anatomical images do not need to be acquired for the present patient (A) (column 2, line 1- column 4, line 55); image data is scaled by moving pixels (shifting, rotating, stretching, or compressing the model on a screen output, column 3, lines 40-45), these scaling techniques include both

linear and nonlinear techniques; deforming the image by minimizing distance between points, and accepting the minimization even when the distance between the points is not zero (it is well known to accept computations with a small amount of error, i.e. not zero, for example as illustrated by Fox et al., [0108]); measurements performed on a plurality of test persons and selecting the standard model from a library of images from a plurality of different people (actual vertebra image data sets, column 2, lines 35-50).

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have combined previous image data with the present patient's data as taught by Vilsmeier, in the system of Fox et al., with the motivation that this will spare the patient the radiation load, and the costs of producing the data set can be saved (Vilsmeier, column 2, lines 1-20). Although Vilsmeier does not specifically mention transcranial magnetic stimulation, there is a reasonable expectation of success to combine these references, because both are related to three-dimensional modeling of the human body for medical techniques.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fox et al. (US 2003/0050527) in view of Vilsmeier (US 7194295) as applied to claim 1 above, and further in view of Krause et al. (US 6711432).

Krause et al. disclose a computer-aided orthopedic surgery system. Krause et al. teach that a database of models can store different templates based on a person's age (column 5, line 55-column 6, line 10).

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have stored different templates based on a person's age as taught by Krause et al. in the combined system of Fox et al. and Vilsmeier. Vilsmeier teaches that there will be a plurality of different models, and that a model is chosen which best fits the patient-characteristic data (column 2, lines 40-50). Age is a common patient-characteristic data which can be stored for a model database as taught by Krause et al., because people of the same/similar age will have more similar data. For example, if the patient were a young child, the model of a similarly aged young child would typically fit better than the model of an adult.

Response to Arguments

Applicant's arguments filed 4/3/08 have been fully considered but they are not persuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., not requiring the patient's head to be immobilized, or using a specific type of model, such as a generic model) are not recited in the rejected claim(s). Although the

claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

In response to applicant's arguments that Fox et al. and Vilsmeier et al. in combination do not teach or suggest "determining the external dimensions of a second head, and scaling the location data of said internal structures of said first head in three-dimensional space to correlate with said external dimensions of said second head to define the locations of the at least one internal structure in said second head; whereby the location data of the internal structures of said second head become modeled without the need for anatomical images of said second head", examiner respectfully disagrees. Fox et al. show obtaining anatomical (internal) and functional images of a patient's head and obtaining external dimensions of a patient's head with the use of a 3-D digitizer, as well as combining all of this data into one model and using it to guide TMS delivery. Vilsmeier teaches that a generic model can be used to avoid obtaining additional anatomical images, and that it can be scaled to fit and then fused with actual patient data. Therefore, one of ordinary skill in the art would have replaced the acquisition of anatomical images by Fox et al. with a model as taught by Vilsmeier, in order to reduce the radiation load to the patient.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan G. Cwern whose telephone number is (571)270-1560. The examiner can normally be reached on Monday through Friday 9:30AM - 6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jonathan G Cwern/
Examiner, Art Unit 3737

/Ruth S. Smith/
Primary Examiner, Art Unit 3737